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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/037,036      | 10/25/2001  | Jonathan S. Stinson  | S63.-9919           | 5380             |

490 7590 01/29/2004

VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER

NGUYEN, VI X

ART UNIT PAPER NUMBER

3731

DATE MAILED: 01/29/2004

5

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

10/037,036

Applicant(s)

STINSON, JONATHAN S.

Examiner

Victor X Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2-4 . 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-23 are rejected under 35 U.S.C. 102 (a) as being anticipated by Stinson (U.S. 6,245,103).

Stinson discloses in figs 1, 4 and col.7, lines 54-67, col. 8, lines 1-17, a process for forming a stent having all the limitations of claims 1-2, 12,15,17-18 and 21-22, including: the process comprises the step of forming a tubular stent (10); the stent radially expands to produce an expanded diameter stent. The step of annealing the expanded diameter stent that shrinks its diameter to a reduced diameter (see col. 12, lines 25-28). The process further comprises at least one time repeating steps b) and c) in sequence.

Regarding claims 3 and 23, Stinson discloses the stent is formed by molding or etching the polymer material (see col. 1, lines 43-66).

Regarding claims 4-5, Stinson discloses the polymer material is thermoplastic or bioabsorbable polymer (see col. 2, lines 37-60).

Regarding claims 6-7 and 19, Stinson discloses the polymer material is selected from the group consisting of PLA (poly(alpha-hydroxy acid) which is selected from the group consisting of PLA (polyglycolide) (see col. 7, lines 4-52).

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Regarding claims 8-9, Stinson discloses the process has a temperature that is below the glass transition temperature of the polymer material; and wherein the step b) performs at room temperature (see col. 19, lines 22-50).

Regarding claims 10-11, Stinson discloses the process has a temperature that is above the glass transition temperature of the polymer material; and wherein the step c) performs at a temperature 130 degree Celsius to about 160 degree Celsius (see col.3, lines 40-50 and col. 4, lines 4-13).

Regarding claims 13-14, Stinson discloses the stent has a hoop or circular orientation (see figs 1); and wherein the polymer is biodegradable (see col. 2, lines 7-60).

Regarding claims 16-20, Stinson discloses a medical device (see fig. 4) adapted for body lumen navigation.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 13, 15, 17 and 21 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Andrews et al. (U.S.6,156,254) in view of Lennard et al (U.S. 4,911,165)

Andrews et al show in fig. 10, a process having all the limitations of claims 1, 13, 15, 17 and 21, including: the step of forming a tubular stent (10); the stent radially expands to produce

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an expanded diameter stent. However, Andrews et al do not disclose the step of annealing the expanded diameter stent that shrinks its diameter to a reduced diameter (see col. 12, lines 25-28).

Lennard et al teach using polypropylene filaments then annealed in an oven and allowed to shrink from about certain percent of the original length (see col. 4, lines 55-65).

It would have been obvious to one having ordinary skill in the art at the same time the invention was made to modify Andrews et al by adding polypropylene filaments then annealed in an oven and allowed to shrink as taught by Lennard et al et al in order to reduce the initial stretching and to allow the material to become constricted from heat or cold temperature. Furthermore, it will increase the final molecular orientation of the stent.

### *Conclusion*

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 6,149,680 to Shelso

U.S. Pat. No. 5,484,444 to Braunschweiler

U.S. Pat. No. 6,626,939 to Burnside

U.S. Pat. No. 6,174,330 to Stinson

U.S. Pat. No. 5,527,337 to Stack

U.S. Pat. No. 5,674,277 to Freitag

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Victor X Nguyen

Examiner

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Vn *VN*

January 21, 2004

  
MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700